United States District Court

EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ORTHOACCEL TECHNOLOGIES, INC.	§	
	§	
v.	§	Civil Action No. 4:16-cv-00350-ALM
	§	Judge Mazzant
PROPEL ORTHODONTICS, LLC	§	
	§	

MEMORANDUM OPINION AND ORDER

Pending before the Court is Propel Orthodontics, LLC's Motion for Partial Summary Judgment Regarding the Benefits of the VPro5 (Dkt. #268). The Court, having considered the relevant pleadings, finds Propel Orthodontics, LLC's motion is denied.

BACKGROUND

Plaintiff, OrthoAccel Technologies, Inc. ("OrthoAccel"), is a medical device company that manufactures dental appliances. In 2008, OrthoAccel developed a prototype hands-free dental device that uses gentle vibrations to accelerate tooth movement when used with orthodontic treatment. This prototype would eventually become the AcceleDent device, which has two main functional components: (1) a "Mouthpiece" and (2) an "Activator." The Activator is a small extraoral component that generates a vibrational force of 0.25N at 30 Hz. The Activator connects directly to the Mouthpiece, which the patient lightly bites down on for 20 minutes daily to accelerate tooth movement during orthodontic treatment.

On November 5, 2011, the Food and Drug Administration ("FDA") granted 510(k) clearance for AcceleDent as "an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement." A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective as a legally marketed device (a

"predicate device") that is not subject to premarket approval. 510(k) clearance is required for Class II devices, but Class I devices are 510(k) exempt. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as a Class I device. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Dental implants and braces are examples of Class II devices.

In 2012, OrthoAccel launched its Class II AcceleDent device in the United States to be used in conjunction with orthodontic treatment. In 2013, OrthoAccel launched the AcceleDent Aura ("Aura"), the second generation of AcceleDent, which initially was cleared to be used with braces only. OrthoAccel offers its customers special pricing through its AcceleDent NOW Program ("ADNow"). The ADNow agreements require doctors to offer the AcceleDent device to all patients in their practice and keep a certain number of units in stock. As of January 12, 2017, OrthoAccel had 127 providers signed up for the ADNow program.

Defendant Propel Orthodontics, LLC ("Propel") is also a medical device company that manufactures dental appliances. In January 2016, Propel began marketing a vibratory Class I device designed to help seat clear aligners. Orthodontic patients wear a series of these removable aligners, marketed under names such as Invisalign and ClearCorrect, to gradually straighten their teeth. In March 2016, Propel released the VPro5, which operates at 120 Hz and requires five minutes of daily use to properly seat (i.e., fit better on the teeth) clear aligners. The VPro5 costs significantly less than the OrthoAccel Aura. On July 8, 2016, OrthoAccel's product—the Aura—was cleared for use with clear aligners.

Propel primarily markets the VPro5 through its sales force in a consultative setting. Propel sales representatives originally promoted the VPro5 by telling orthodontists that the device offers

several clinical benefits ("5 Clinical Benefits"). These 5 Clinical Benefits include: (1) more efficient aligner seating, (2) relieves orthodontic pain, (3) accelerates tooth movement, (4) fast tracks retention, and (5) stimulates bone growth and remodeling. Propel's sales force originally marketed the VPro5 as a quicker, cheaper alternative to the AcceleDent device.

In May 2016, OrthoAccel sued Propel, claiming Propel falsely advertised the VPro5's 5 Clinical Benefits in violation of the Lanham Act. On October 3, 2016, Propel filed its counterclaims against OrthoAccel (Dkt. #118). On October 26, 2016, the Court entered a preliminary injunction enjoining Propel from advertising the 5 Clinical Benefits (Dkt. #148). On January 13, 2017, Propel filed this Motion for Partial Summary Judgment Regarding the Benefits of the VPro5 (Dkt. #268). On January 27, 2017, OrthoAccel filed a response (Dkt. #277). On February 6, 2017, Propel filed a reply (Dkt. #280). On February 14, 2017, OrthoAccel filed a sur-reply (Dkt. #292).

LEGAL STANDARD

The purpose of summary judgment is to isolate and dispose of factually unsupported claims or defenses. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986). Summary judgment is proper under Rule 56(a) of the Federal Rules of Civil Procedure "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute about a material fact is genuine when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 248 (1986). Substantive law identifies which facts are material. *Id.* The trial court "must resolve all reasonable doubts in favor of the party opposing the motion for summary judgment." *Casey Enters., Inc. v. Am. Hardware Mut. Ins. Co.*, 655 F.2d 598, 602 (5th Cir. 1981).

The party seeking summary judgment bears the initial burden of informing the court of its motion and identifying "depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials" that demonstrate the absence of a genuine issue of material fact. Fed. R. Civ. P. 56(c)(1)(A); *Celotex*, 477 U.S. at 323. If the movant bears the burden of proof on a claim or defense for which it is moving for summary judgment, it must come forward with evidence that establishes "beyond peradventure *all* of the essential elements of the claim or defense." *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986). Where the nonmovant bears the burden of proof, the movant may discharge the burden by showing that there is an absence of evidence to support the nonmovant's case. *Celotex*, 477 U.S. at 325; *Byers v. Dall. Morning News, Inc.*, 209 F.3d 419, 424 (5th Cir. 2000). Once the movant has carried its burden, the nonmovant must "respond to the motion for summary judgment by setting forth particular facts indicating there is a genuine issue for trial." *Byers*, 209 F.3d at 424 (citing *Anderson*, 477 U.S. at 248–49). A nonmovant must present affirmative evidence to defeat a properly supported motion for summary judgment. *Anderson*, 477 U.S. at 257. Mere denials of material facts, unsworn allegations, or arguments and assertions in briefs or legal memoranda will not suffice to carry this burden. Rather, the Court requires '"significant probative evidence'" from the nonmovant to dismiss a request for summary judgment. *In re Mun. Bond Reporting Antitrust Litig.*, 672 F.2d 436, 440 (5th Cir. 1982) (quoting *Ferguson v. Nat'l Broad. Co.*, 584 F.2d 111, 114 (5th Cir. 1978)). The Court must consider all of the evidence but "refrain from making any credibility determinations or weighing the evidence." *Turner v. Baylor Richardson Med. Ctr.*, 476 F.3d 337, 343 (5th Cir. 2007).

ANALYSIS

Propel asks the Court to grant summary judgment on OrthoAccel's claim that Propel violated the Lanham Act in advertising the VPro5's 5 Benefits. Specifically, Propel claims OrthoAccel has not evidenced literal falsity under Section 43(a) of the Lanham Act and Texas common law unfair competition. Propel contends that OrthoAccel has not carried its burden in demonstrating that the 5 Benefits are literally false because OrthoAccel has produced no study or test to prove that the VPro5 cannot offer the advertised benefits. But when a "defendant's promotion implicitly or explicitly refers to tests or data, a plaintiff can satisfy its burden of proving that the promotion is literally false by demonstrating that the tests are not sufficiently reliable to permit a person to conclude with reasonable certainty that they established the claim made." *Pamlab, LLC v. Macoven Pharm., LLC*, 881 F. Supp. 2d 470, 467 (S.D.N.Y. 2012); *see Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230 (5th Cir. 2014) (finding falsity where plaintiff established that competitors' tests were not scientifically reliable); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1138 (4th Cir. 1993) (finding plaintiff properly pleaded false advertising on generic drug where plaintiff alleged "that bioequivalence studies either had not been performed or had been performed on a drug manufactured differently from the one advertised"). The Court previously determined that the VPro5's advertising claims were literally false because Propel's alleged support was irrelevant and unreliable. Thus, there is at least a genuine issue of material fact regarding whether Propel's studies, tests, and data support their advertising claims.[1]

[1] Propel argues "the Court should grant Propel's Motion for Partial Summary Judgment Regarding the Benefits of the VPro5 in its entirety," but Propel ignores that if OrthoAccel were unable to prove literal falsity, the same evidence would be submitted to the jury to determine whether the claims were misleading. *See Logan v. Burgers Ozark Country Cured Hams, Inc.*, 263 F.3d 447, 462 (5th Cir. 2001).

CONCLUSION

After a careful review of the record and the arguments presented, the Court is not convinced that there are no material issues of fact entitling Propel to judgment as a matter of law on OrthoAccel's false advertising claims related to the VPro5's 5 Benefits. This claim should proceed to trial.

It is therefore **ORDERED** that Propel Orthodontics, LLC's Motion for Partial Summary Judgment Regarding the Benefits of the VPro5 (Dkt. #268) is hereby **DENIED**.

SIGNED this 26th day of April, 2017.

AMOS L. MAZZANT
UNITED STATES DISTRICT JUDGE